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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/752,095

01/07/2004

Bill E. Cham

P07389US01/BAS

2329

881 7590 03/14/2007

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/752,095

Applicant(s)

CHAM, BILL E.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-29, 33-39, 43-50 and 54-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Guerrero (U.S. Patent No. 3,960,839).

Guerrero discloses purification of a glycoalkaloid composition (column 3, lines 19-35). The removal of free sugars would have been inherent in the process disclosed by Guerrero.

Claims 24-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerrero (U.S. Patent No. 3,960,839) in combination with Cham et al (Cancer Letters, 55 (1990) 221-225).

Guerrero discloses purification of glycoalkaloids (column 3, lines 19-35) but do not disclose pharmaceutical compositions comprising glycoalkaloids and their use for treating cancer. However, since Cham et al disclose a composition comprising glycoalkaloids useful for treating cancer (page 221), it would have been within the

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ordinary skill in the art at the time the present invention was made to use purified glycoalkaloids in a pharmaceutical composition for treating cancer.

Claims 40, 41, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerrero (U.S. Patent No. 3,960,839) or Cham et al (Cancer Letters, 55 (1990) 221-225) in view of Gatti et al (U.S. Patent No. 5,124,318).

Each of Guerrero and Cham et al discloses a glycoalkaloid composition but do not disclose said composition in combination with a liquid carrier such as DMSO, acetic acid or lactic acid or with a stabilizing agent. However, since Gatti et al conventional use of acetic acid and stabilizing agents in an injectable composition comprising glycosides (column 4) and He, a person having ordinary skill in the art at the time the claimed invention was made to add conventional additives disclosed by Gatti et al to a composition disclosed by Guerrero or Cham et al.

Claims 30, 31, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerrero et al (U.S. Patent No. 3,960,839) in view of Daniels et al (U.S. Patent No. 4,053,591).

Guerrero discloses purification of glycoalkaloids (column 3, lines 19-35) but do not disclose the use of chloroform. However, since the use of chloroform in the purification process was well known in the art at the time the claimed invention was made as disclosed by Daniels et al (column 14, lines 50-52), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to use chloroform in the purification process disclosed by Guerrero.

Applicant's arguments filed January 23, 2007 have been fully considered but they are not persuasive.

Applicant contends that Guerrero does not teach or suggest any process or method which would remove free sugars, which are degradation products of a glycoalkaloid, as claimed. Applicant further contends that Guerrero separates impurities from an alcoholic solution of solasodine glycosides by increasing or decreasing the volume of water to induce precipitation and that free sugars are highly water soluble and thus will remain in solution. This argument has not been found persuasive. The present claims are directed to a method of preparing a glycoalkaloid preparation which includes the step of removing free sugars being degradation products such as by washing the extract with an aqueous solvent as set forth in claim 29. Further, In Example 1 on page 17 of the specification, free sugars are removed by washing with water. The addition of water disclosed by Guerrero is not seen to be different from the washing with water as encompassed by the present claims. Applicant has not provided any evidence that at least some free sugars have not been removed by the process disclosed by Guerrero.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

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